

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

JOHN E. BRODIE,

Plaintiff,

vs.

NOVARTIS PHARMACEUTICALS
CORPORATION,

Defendant.

Civil Action No.: 1:06-CV-1906

Electronically Filed

**ANSWER AND DEFENSES OF
DEFENDANT NOVARTIS
PHARMACEUTICALS
CORPORATION TO PLAINTIFF'S
COMPLAINT**

JURY DEMAND

Defendant Novartis Pharmaceuticals Corporation ("NPC") responds to plaintiff's
Complaint ("the Complaint") as follows:

1. The allegations in Paragraph 1 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint and therefore denies the same. NPC denies that any injuries alleged in the Complaint were caused by Zometa[®].

2. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 2 of the Complaint and therefore denies the same.

3. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts is "at all times herein mentioned" and therefore NPC is unable to respond to the allegations in Paragraph 3 of the Complaint. To the extent a response is required, NPC admits that it is a corporation incorporated under the laws of the state of Delaware with its principal offices located in East Hanover, New Jersey. NPC denies the remaining allegations in Paragraph 3 of the Complaint.

4. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts is “at all times herein mentioned” and therefore NPC is unable to respond to the allegations in Paragraph 4 of the Complaint. To the extent a response is required, NPC admits that it does business in the State of New York and the State of Missouri. NPC denies the remaining allegations in Paragraph 4 of the Complaint.

5. The allegations in Paragraph 5 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 5 of the Complaint and therefore denies the same. NPC denies the remaining allegations in Paragraph 5 of the Complaint.

6. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts in Paragraph 6. To the extent a response is required, NPC admits that it labels, tests, advertises, markets, promotes, distributes, and sells Zometa[®]. NPC denies the remaining allegations in Paragraph 6 of the Complaint.

7. In response to Paragraph 7 of the Complaint, NPC admits that Zometa[®] is a brand name under which NPC sells zoledronic acid. NPC admits that Zometa[®] is a bisphosphonic acid. NPC admits that Zometa[®] is given intravenously to cancer patients. NPC denies the remaining allegations in Paragraph 7 of the Complaint.

8. In response to Paragraph 8 of the Complaint, NPC states Zometa[®] is approved by the Food and Drug Administration (“FDA”) for the indications listed on each product’s label. NPC denies the remaining allegations in Paragraph 8 of the Complaint to the extent that they mischaracterize or misstate information contained on the label for Zometa[®].

9. NPC lacks sufficient knowledge or information to determine the meaning of the term “product literature” and what time periods plaintiff asserts in Paragraph 9. Therefore, NPC is unable to respond to the allegations in Paragraph 9 of the Complaint. To the extent that a response is required, NPC denies the allegations in Paragraph 9 of the Complaint.

10. NPC admits that it received a single case report from a physician in December 2002 regarding alleged osteonecrosis of the jaw in a patient given Zometa[®]. NPC denies the remaining allegations in Paragraph 10 of the Complaint.

11. NPC admits that in 2004, Dr. Ruggerio and others published an article entitled “Osteonecrosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 cases,” in the Journal of Oral and Maxillofacial Surgery. NPC admits that the quoted language appears in this article, but avers that the article speaks for itself. NPC denies the remaining allegations in Paragraph 11 of the Complaint to the extent that they mischaracterize or misstate information contained in said article.

12. The allegations in Paragraph 12 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC admits that it sent correspondence to medical professionals in September 2004 and May 2005 addressing the subject of osteonecrosis of the jaw. NPC denies the remaining allegations in Paragraph 12 of the Complaint.

13. NPC lacks sufficient knowledge or information to determine whether plaintiff was given and/or injected with Zometa[®] and if plaintiff suffered any injury. NPC denies the remaining allegations in Paragraph 13 of the Complaint.

14. NPC lacks sufficient knowledge or information to determine whether plaintiff was given and/or injected with Zometa[®] and if plaintiff developed osteonecrosis of the jaw. The

remaining allegations in Paragraph 14 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 14 of the Complaint.

15. NPC lacks sufficient knowledge or information to determine whether plaintiff was given and/or injected with Zometa[®] and if plaintiff suffered any injury. The allegations in Paragraph 15 of the Complaint at subparts (a) through (g) constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 15 of the Complaint. NPC denies that plaintiff suffered any injuries or is entitled to any of the relief asserted in subparts (a) through (g) of Paragraph 15.

16. In response to Paragraph 16 of the Complaint, NPC incorporates by reference its responses to the allegations in Paragraphs 1-15 of the Complaint.

17. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts in Paragraph 17. To the extent a response is required, NPC admits that it labels, markets, tests, distributes, and sells Zometa[®]. NPC denies the remaining allegations in Paragraph 17 of the Complaint.

18. The allegations in Paragraph 18 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 18 of the Complaint.

19. The allegations in Paragraph 19 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 19 of the Complaint.

20. The allegations in Paragraph 20 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 20 of the Complaint.

21. The allegations in Paragraph 21 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 21 of the Complaint.

22. NPC lacks sufficient knowledge or information to determine whether plaintiff was given and/or injected with Zometa[®] and if plaintiff suffered any injury. The allegations in Paragraph 22 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 22 of the Complaint.

23. In response to Paragraph 23 of the Complaint, NPC incorporates by reference its responses to the allegations in Paragraphs 1-15 of the Complaint.

24. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts in Paragraph 24. To the extent a response is required, NPC admits that it labels, markets, tests, distributes, and sells Zometa[®]. NPC denies the remaining allegations in Paragraph 24 of the Complaint.

25. The allegations in Paragraph 25 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 25 of the Complaint.

26. The allegations in Paragraph 26 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 26 of the Complaint.

27. NPC lacks sufficient knowledge or information to determine whether plaintiff suffered any injury. The allegations in Paragraph 27 constitute legal conclusions to which no response is required. To the extent that a response is required NPC denies the allegations in Paragraph 27 of the Complaint.

28. In response to Paragraph 28 of the Complaint, NPC incorporates by reference its responses to the allegations in Paragraphs 1-15 of the Complaint.

29. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts in Paragraph 29. To the extent a response is required, NPC admits that it labels, markets, tests, distributes, and sells Zometa[®]. NPC denies the remaining allegations in Paragraph 29 of the Complaint.

30. The allegations in Paragraph 30 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 30 of the Complaint.

31. The allegations in Paragraph 31 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 31 of the Complaint.

32. The allegations in Paragraph 32 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 32 of the Complaint.

33. NPC lacks sufficient knowledge or information to determine whether plaintiff suffered any injury. The allegations in Paragraph 33 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 33.

34. In response to Paragraph 34 of the Complaint, NPC incorporates by reference its responses to the allegations in Paragraphs 1-15 of the Complaint.

35. The allegations in Paragraph 35 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 35 of the Complaint.

36. The allegations in Paragraph 36 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 36 of the Complaint and therefore denies the same.

37. The allegations in Paragraph 37 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 37 of the Complaint.

38. NPC lacks sufficient knowledge or information to determine whether plaintiff suffered any injury. The allegations in Paragraph 38 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 38.

39. In response to Paragraph 39 of the Complaint, NPC incorporates by reference its responses to the allegations in Paragraphs 1-15 of the Complaint.

40. The allegations in Paragraph 40 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 40 of the Complaint.

41. The allegations in Paragraph 41 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information

to form a belief as to the truth of the allegations in Paragraph 41 of the Complaint and therefore denies the same.

42. The allegations in Paragraph 42 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 42 of the Complaint.

43. NPC lacks sufficient knowledge or information to determine whether plaintiff suffered any injury. The allegations in Paragraph 43 constitute legal conclusions to which no response is required. To the extent that a response is required NPC denies the allegations in Paragraph 43 of the Complaint.

44. With respect to the allegations of the unnumbered paragraph and its subparts (a) through (c) following Paragraph 43, which begins with the words “WHEREFORE,” these allegations constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies that plaintiff is entitled to any of the relief requested therein.

45. Every allegation in the Complaint that is not specifically and expressly admitted in this Answer is hereby specifically and expressly denied.

AFFIRMATIVE DEFENSES

1. The Complaint, in whole or in part, fails to state a claim or cause of action against NPC upon which relief can be granted.

2. Venue is inconvenient to the parties in the United States District Court for the Southern District of New York, and this matter should be transferred to its appropriate jurisdiction.

3. The doctrines contained in Restatement (Second) of Torts § 402A, Comment K, bar plaintiff's claims against NPC in whole or in part.

4. The doctrine(s) contained in Restatement (Third) of Torts, Product Liability, §4 and §6, bar plaintiff's claims against NPC in whole or in part.

5. Applicable statutes of limitations bar plaintiff's claims in whole or in part.

6. Plaintiff's misuse or abnormal use of the product or failure to follow instructions bars the plaintiff's claims in whole or in part.

7. If plaintiff used a product sold by NPC, then plaintiff's claims are barred, in whole or in part, because plaintiff assumed the risks disclosed by the product labeling, by the prescribing physicians, or by other persons or entities.

8. Any alleged negligent or culpable conduct of NPC, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of plaintiff's alleged injuries.

9. If plaintiff used a product sold by NPC, plaintiff used the product for "off-label" purposes, which bars the plaintiff's claims.

10. The "learned intermediary" doctrine bars plaintiff's claims.

11. Plaintiff's claims are barred, in whole or in part, because the products at issue were designed, manufactured, marketed and labeled with proper warnings, information, cautions and instructions, in accordance with the state of the art and the state of scientific and technological knowledge.

12. Plaintiff's claims are barred, in whole or in part, because the products at issue were not defective or unreasonably dangerous in that they complied with, at all relevant times, all applicable government safety standards.

13. Plaintiff's claims are preempted, in whole or in part, by applicable federal law relating to the design, testing, producing, manufacturing, labeling, distributing, modeling, processing, and supply of Zometa[®].

14. Plaintiff's claims are barred, in whole or in part, because plaintiff's injuries, if any, were the result of conduct of plaintiff, independent third parties, and/or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening and superseding causes of the alleged injuries, including but not limited to plaintiff's pre-existing medical conditions.

15. If plaintiff suffered injury or damages as alleged, which is denied, such injury or damage resulted from acts or omissions of persons or entities for which NPC is neither liable nor responsible or resulted from diseases and/or causes that are not related or connected with any product sold, distributed, or manufactured by NPC. Such acts or omissions on the part of others or diseases or causes constitute an independent, intervening and sole proximate cause of plaintiff's alleged injury or damages.

16. Plaintiff's claims are barred, in whole or in part, because plaintiff's alleged injuries, if caused by Zometa[®], which is denied, were the result of plaintiff's own idiosyncratic reactions.

17. Plaintiff failed to mitigate, which limits plaintiff's damages, if any, in whole or in part.

18. NPC has no legal relationship or privity with plaintiff and owes no duty to plaintiff by which liability could be attributed to it.

19. NPC made no warranties of any kind, express or implied, or any representations of any nature whatsoever to plaintiff. If any such warranties were made, whether express or implied, which NPC specifically denies, then plaintiff failed to give notice of any breach thereof.

20. Plaintiff's causes of action are barred in whole or in part by plaintiff's own contributory/comparative negligence.

21. Plaintiff is responsible, in whole or in part, for any injuries he suffered as a result of his own negligence and his acts or omissions bar his recovery to the extent that his individual relative degree of fault is equal to or greater than the fault of NPC, no fault being admitted. In the alternative, if plaintiff's individual relative degree of fault is less than that of NPC, no fault being admitted, then plaintiff's right to recover is diminished in an amount based upon their individual relative degree of fault.

22. Plaintiff's recovery, if any, shall be reduced by those payments that plaintiff receives from collateral sources.

23. If plaintiff has been injured or damaged, no injury or damages being admitted, an NPC product did not cause such injuries.

24. NPC hereby gives notice that it intends to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserves its right to amend this Answer to assert such defenses.

WHEREFORE, Defendant Novartis Pharmaceuticals Corporation demands judgment dismissing plaintiff's Complaint, together with costs and all further relief as this Court deems just and proper.

Dated: April 6, 2006

Respectfully submitted,

s/ Ethan D. Stein

Diane E. Lifton (DL-9673)

Ethan D. Stein (ES-7130)

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CERTIFICATE OF SERVICE

I hereby certify that on April 6, 2006, the Answer and Defenses of Defendant Novartis Pharmaceuticals Corporation to Plaintiff's Complaint was filed with the Clerk of the Court and served in accordance with the Southern District's Rules on Electronic Service upon the following parties and participants:

Daniel A. Osborn, Esq.
Beatie and Osborn LLP
521 Fifth Avenue, 34th Floor
New York, NY 10175

I further certify that I have this 6th day of April 2006 served a true and correct copy of the Answer and Defenses of Defendant Novartis Pharmaceuticals Corporation to Plaintiff's Complaint, by United States Mail, postage prepaid, on:

The Powell Law Firm, L.C.
269 South Beverly Drive
Suite 1156
Beverly Hills, CA 90212

The Offices of Jeffrey C. Bogert
501 Colorado Boulevard
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Santa Monica, CA 90401

s/ Ethan D. Stein
Ethan D. Stein